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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT J. CROWLEY

Appeal 2008-5136[1]
Application 09/879,433
Technology Center 3700

Decided:[2] February 27, 2009

Before TONI R. SCHEINER, DEMETRA J. MILLS, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

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[1] The real party in interest is Boston Scientific Corporation.

[2] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 14-40, all the claims pending in the application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

Claims 14, 27, and 28 are representative of the subject matter on appeal:

14. A method for ablating mucosal or endothelial lining, comprising:
a) providing a light device comprising a flash lamp;
b) inserting the light device inside a body near a mucosal or endothelial lining to be ablated, the mucosal or endothelial lining being on top of a muscle layer;
c) energizing the flash lamp to generate a high intensity ultraviolet light; and
d) ablating the mucosal or endothelial lining with the generated light, and avoiding causing substantial damage to the muscle layer underneath.

27. The method of claim 14 further comprising characterizing a targeted portion of the mucosal or endothelial lining by transporting a dye to the mucosal or endothelial lining to stain the targeted portion and wherein the step of ablating the mucosal or endothelial lining comprises using light absorbed by the stained portion.

28. The method of claim 14 further comprising introducing a drug near the mucosal or endothelial lining and activating the drug through the light.

The Examiner relies on the following evidence:

Stanton	US 3,970,394	Jul. 20, 1976
Feinbloom	US 4,662,733	May 5, 1987
Spears	US 4,799,479	Jan. 24, 1989
Clarke	US 5,053,033	Oct. 1, 1991
Selman et al. (Selman)	US 5,405,369	Apr. 11, 1995
Ohtake	US 5,617,163	Apr. 1, 1997
Anderson et al. (Anderson)	US 5,814,041	Sep. 29, 1998
Waksman et al. (Waksman)	US 5,899,882	May 4, 1999

The Examiner rejected the claims as follows:

I. Claims 14-18, 21, 22, 25, 27, 28, 39, and 40 under 35 U.S.C. § 103(a) as unpatentable over Selman and Clarke.

II. Claims 20, 23, and 24 under 35 U.S.C. § 103(a) as unpatentable over Selman, Clarke, and Waksman.

III. Claims 26, 29, and 30 under 35 U.S.C. § 103(a) as unpatentable over Selman, Clarke, Waksman, and Spears.

IV. Claims 33 and 34 under 35 U.S.C. § 103(a) as unpatentable over Selman, Clarke, and Feinbloom.

V. Claims 35 and 36 under 35 U.S.C. § 103(a) as unpatentable over Selman, Clarke, Feinbloom, and Stanton.

VI. Claims 14, 19, and 37-39 under 35 U.S.C. § 103(a) as unpatentable over Anderson and Clarke.

VII. Claims 31 and 32 under 35 U.S.C. § 103(a) as unpatentable over Anderson, Clarke, and Ohtake.

We affirm.

OBVIOUSNESS: SELMAN AND CLARK

THE ISSUE

The principal issue common to all five of the rejections based on the combined teachings of Selman and Clarke is whether Appellant has established that the Examiner erred in concluding that it would have been obvious for one skilled in the art to ablate a mucosal or endothelial lining overlying a muscle layer, while avoiding damage to the underlying muscle layer, by illuminating the mucosal or endothelial lining with ultraviolet light generated by a flash lamp, rather than a laser.

FINDINGS OF FACT

FF1 Independent claim 14 is directed to a method of ablating a mucosal or endothelial lining overlying a muscle layer, while avoiding substantial damage to the muscle layer, by illuminating the mucosal or endothelial lining with a flash lamp energized to generate high intensity ultraviolet light.

FF2 The claimed method may include staining the mucosal or endothelial lining with a dye, and using light absorbed by the dye to ablate the lining (dependent claim 27), or introducing a light-activated composition near the mucosal or endothelial lining and activating the composition by illuminating the lining (dependent claim 28).

FF3 According to the Specification,

> Application of high intensity ultraviolet light ablates mucosal linings without damaging tissue underneath the linings such as the muscularis, because [the] ultraviolet component of the light is greatly attenuated by tissue. Ultraviolet light is absorbed through only a short distance before it is converted to heat. Therefore, ultraviolet light is particularly effective in destroying the top-most layer of cells, which is the target in ablation of mucosal linings

(Spec. 9).

Selman

FF4 Selman describes selectively ablating a mucosal layer (e.g., in the bladder or bowel), without damaging underlying muscle, by staining the mucosal layer with a photosensitive compound, and then illuminating the mucosal lining with light, including ultraviolet light, to initiate a series of chemical reactions which preferentially damages or destroys the stained

tissue. The underlying muscle tissue does not absorb the photosensitive compound in sufficient amounts to cause damage, and is spared during the illumination (Selman, col. 3, ll. 37-56; col. 6, ll. 37-41).

FF5 The only difference between Selman and the claimed invention is that Selman does not specifically teach using a flash lamp as the source of illumination. However, Selman teaches that illumination "can be achieved by delivering electromagnetic radiation energy from conventional light source" (Selman, col. 7, ll. 21-24), "such as a laser, LED device, or lamp" (*id.* at col. 9, l. 18).

FF6 Selman teaches that determination of the appropriate intensity, wavelength and duration of the illuminating energy is based at least in part on the type and amount of photosensitive compound used (Selman, col. 9, ll. 50-53). It is evident from Selman that such a determination is within the level of skill in the art.

Clarke

FF7 Clarke describes a method of preventing restenosis following angioplasty. After a vessel-obstructing plaque or lesion is ablated by ultraviolet light, or displaced by balloon angioplasty, ultraviolet light is used to kill smooth muscle cells within the blood vessel at the angioplasty site, "without damaging either the inner endothelium layer . . . or the outer adventitia . . . of the blood vessel" (Clarke, col. 3, ll. 19-41; col. 5, ll. 3-5).

FF8 Clarke's method does not involve photosensitive compounds.

FF9 Clarke teaches that "[v]arious UV radiation sources can be used" to kill the target muscle cells (Clarke, col. 2, l. 51), including various lasers and "a UV flash lamp" (*id.* at col. 2, l. 62).

Feinbloom

FF10 The Examiner finds that "Feinbloom teaches a flash lamp circuit that uses a transformer to step up the voltage" (Ans. 6), to "provide[ ] a bright light" (*id.*). Appellant has not disputed this finding.

Stanton

FF11 The Examiner finds that "Stanton teaches the use of a foil as a triggering electrode for a flash lamp" (Ans. 6). Appellant has not disputed this finding.

PRINCIPLES OF LAW

The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, ___, 127 S. Ct. 1727, 1742 (2007). "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at 1739. Moreover, "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 1742. Finally, an "[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious." *In re Fout*, 675 F.2d 297, 301 (CCPA 1982).

Arguments not made are waived. *See* 37 C.F.R. § 41.37(c)(1)(vii) ("[A]rguments or authorities not included in the brief or a reply brief . . . will be refused consideration by the Board, unless good cause is shown.").

ANALYSIS AND CONCLUSIONS OF LAW

I. Selman and Clarke

The Examiner rejected claims 14-18, 21, 22, 25, 27, 28, 39, and 40 as unpatentable over Selman and Clarke. Claims 15-18, 21, 22, 25, 27, 28, 39, and 40 were not separately argued, therefore, we select claim 14 as representative for purposes of deciding the issues raised by this rejection. *See* C.F.R. 41.37(c)(1)(vii).

The Examiner concluded that "[i]t would have been obvious to the artisan of ordinary skill to employ the flash lamp of Clarke as the source [of ultraviolet light] in the method of Selman et al, since th[e] [flash lamp] is equivalent to the laser as taught by Clarke and since Selman et al teach that any of a variety of light sources can be used" (Ans. 4[3]). The Examiner's

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[3] The Examiner's Answer is not paginated - the numbers used here are based on the assumption that the title page is the first page.

position is essentially that "the absorption of the light in Selman et al is controlled by the [location of the] photosensitive dye" and "the principle of operation of Selman is preserved regardless of the ultraviolet source employed: the dye is absorbed into the tissue to be destroyed, the dye absorbs the light, and the tissue is destroyed" (*id.* at 7).

Appellant contends that Selman and Clarke "cannot reasonably be combined" (App. Br. 11), because they take "dissimilar approaches" (*id.*) and "target layers that are mutually exclusive" (*id.* at 11-12). Specifically, Appellant contends that "Selman is concerned with photodynamic treatment, which relies on tissue's absorption of . . . [photosensitive] compositions . . . in order to be effective" (*id.* at 11), while Clarke "directly radiates tissue without the aid of any drug" (*id.*). Moreover, Appellant contends "[i]n Selman, the mucosal layer is destroyed while the muscle layer is saved" but "in Clarke, it is the smooth muscle layer that is destroyed while the mucosal layer is saved" (*id.* at 12). Thus, Appellant contends, "one skilled in the art . . . would not utilize Clarke's flash lamp for Selman's purpose" (*id.* at 12).

Appellant also contends that the "combination of Selman and Clarke would fail to provide an enabling description of the method . . . [of] Claim 14" (App. Br. 13) because "Selman is silent on any teaching of UV radiation outside the realm of photodynamic treatment, and Clarke teaches that UV radiation is ineffective against the endothelial lining but effective on smooth muscle cells" (*id.*).

Appellant's arguments are not persuasive. Selman and Clarke provide evidence that one skilled in the art of tissue ablation would have been familiar with the destructive effect of ultraviolet light on tissue in general,

with or without the use of a photosensitive dye (**FF4**, **FF7**). Selman teaches that the selectivity of his method for mucosal tissue is due to preferential absorption of the photosensitive dye by the mucosal layer (**FF4**). We agree with the Examiner that one of skill would have expected Selman's method to be selective for mucosal tissue, regardless of the source of the light, as long as the wavelength and intensity of the light was compatible with the photosensitive dye - which we find would have been within the level of skill in the art to determine (**FF6**).

In any case, Selman teaches that destructive illumination can be achieved by delivering electromagnetic radiation energy from a conventional light source, "such as a laser, LED device, or lamp" (**FF5**), while Clarke teaches that an ultraviolet flash lamp is a conventional alternative to a laser for illuminating tissue (**FF9**). An express suggestion to substitute one for the other is not required to establish obviousness (*In re Fout*, 675 F.2d at 301).

We find that Appellant has not established that the Examiner erred in concluding that the teachings of Selman and Clarke would have led one skilled in the art to ablate a mucosal or endothelial lining overlying a muscle layer, while avoiding damage to the underlying muscle layer, by illuminating the mucosal or endothelial lining with ultraviolet light generated by a flash lamp, rather than a laser.

II. Selman, Clarke, and Waksman

The Examiner rejected claims 20, 23, and 24 as unpatentable over Selman, Clarke, and Waksman.

Appellant contends that "Waksman does not provide any suggestion as to why and how Selman and Clarke's teachings can be combined or modified to provide a step of ablating the mucosal or endothelial lining using UV light generated by a flash lamp while avoiding substantial damage to the muscle layer, as required by instant Claim 14" (App. Br. 15), and therefore does not "remed[y] the deficiency of Selman and Clarke" (*id.*).

This argument is not persuasive, as Appellant has not established that the Examiner erred in concluding that the invention of claim 14 would have been obvious over the teachings of Selman and Clarke for the reasons discussed above.

III. Selman, Clarke, Waksman, and Spears

The Examiner rejected claims 26, 29, and 30 as unpatentable over Selman, Clarke, Waksman, and Spears.

Appellant contends that "Spears does not provide any suggestion as to why and how Selman, Clarke, and Waksman's teachings can be combined or modified to provide a step of ablating the mucosal or endothelial lining using UV light generated by a flash lamp while avoiding substantial damage to the muscle layer, as required by instant Claim 14" (App. Br. 16), and therefore does not "remed[y] the deficiency of Selman, Clarke, and Waksman" (*id.* at 15).

Again, this argument is not persuasive, as Appellant has not established that the Examiner erred in concluding that the invention of claim 14 would have been obvious over the teachings of Selman and Clarke, for the reasons discussed above.

IV. Selman, Clarke, and Feinbloom

The Examiner rejected claims 33 and 34 as unpatentable over Selman, Clarke, and Feinbloom. Claim 33 depends from claim 14 and requires "stepping up the voltage of a power supplied to the flash lamp."

According to the Examiner, "Feinbloom teaches a flash lamp circuit that uses a transformer to step up the voltage" and "[i]t would have been obvious to the artisan of ordinary skill to employ a transformer to step up the voltage [of a flash lamp], since this provides a bright light" (Ans. 6).

Appellant contends that "Feinbloom does not concern medical treatment . . . [and] does not provide any suggestion as to why and how Selman and Clarke's teachings can be combined or modified to provide the steps recited in instant Claim 14" (App. Br. 17), and moreover, "is silent as to why the power supply's voltage should be stepped up in an *in vivo* tissue ablation method" (*id.*).

This argument is not persuasive. As discussed above, Appellant has not established that the Examiner erred in concluding that it would have been obvious to use a UV flash lamp to ablate mucosal tissue based on the teachings of Selman and Clarke. The Examiner cited Feinbloom merely as evidence that transformers are conventionally used to step up the voltage to flash lamps to produce a bright light (**FF10**), and Appellant has not disputed this finding.

V. Selman, Clarke, Feinbloom, and Stanton

The Examiner rejected claims 35 and 36 as unpatentable over Selman, Clarke, Feinbloom, and Stanton. Claim 35 depends from claim 33, and

ultimately from 14 and requires "stepping up the voltage . . . using a separate lead connected to a foil disposed adjacent the flash lamp."

According to the Examiner, "Stanton teaches the use of a foil as a triggering electrode for a flash lamp" and "[i]t would have been obvious to the artisan of ordinary skill to employ the triggering electrode . . . since this would help provide a more evenly distributed flash" (Ans. 6).

Appellant contends that

> Stanton does not concern medical treatment . . . [or] provide reasons why the power supply's voltage should be stepped up in an *in vivo* tissue ablation method. Therefore, Stanton does not provide any suggestion as to why and how the teachings of Selman, Clarke, and Feinbloom can be combined or modified to provide the steps recited in instant Claim 33.

(App. Br. 17-18.)

This argument is not persuasive. As discussed above, Appellant has not established that the Examiner erred in concluding that it would have been obvious to use a UV flash lamp to ablate mucosal tissue based on the teachings of Selman and Clarke. The Examiner cited Feinbloom merely as evidence that transformers are conventionally used to step up the voltage to flash lamps to produce a bright light (**FF10**), and Stanton as evidence that triggering electrodes are likewise conventional (**FF11**) , and Appellant has not disputed these findings.

OBVIOUSNESS: ANDERSON AND CLARKE

The principal issue common to both of the rejections based on the combined teachings of Anderson and Clarke is whether Appellant has established that the Examiner erred in concluding that it would have been obvious for one skilled in the art to ablate a mucosal or endothelial lining overlying a muscle layer, while avoiding damage to the underlying muscle layer, by illuminating the mucosal or endothelial lining with ultraviolet light generated by a flash lamp, rather than a laser.

FINDINGS OF FACT

Anderson

FF12 Anderson discloses selective ablation of endometrial tissue (the mucosal lining of the uterus), without damaging the myometrium (the smooth muscle layer underlying the endometrium), by staining the lining with a photosensitive compound, and illuminating the lining with laser light, including ultraviolet light (Anderson, col. 1, ll. 46-52; col. 2, ll. 29-34 and 61-64; col. 3, ll. 7-8).

FF13 Anderson uses an optical radiator with regions of different, complementary transmissivities and reflectivities to illuminate the target area uniformly (Anderson, col. 1, ll. 55-65).

FF14 Anderson teaches that the method can also be used to illuminate and ablate tissue in the mouth, esophagus, bladder, bronchus, skin, or blood vessels (Anderson, col. 4, ll. 40-43).

FF15 The Examiner finds that Anderson teaches that the light source in photodynamic treatment of photosensitized tissue "is '<u>usually</u> a laser fiber' . . . [an] indication that other sources can be used" (Ans. 8).

Ohtake

FF16 The Examiner finds that Ohtake describes "the use of a lenticular surface which take[s] the form of a Fresnel lens . . . with a flash lamp" (Ans. 6) that "provide[s] a more even distribution of light" (*id.*).

ANALYSIS AND CONCLUSIONS OF LAW

VI. Anderson and Clarke

The Examiner concluded that "[i]t would have been obvious to the artisan of ordinary skill to employ a flash lamp as the light source in the method of Anderson" (Ans. 5), because Anderson teaches "tissue ablation by photodynamic therapy by illuminating a photosensitizer" (*id.* at 8), "wherein the light source is 'usually a laser fiber'" (*id.*), and "wherein the device can employ ultraviolet light" (*id.*), while Clarke "teaches the equivalence of flash lamps and lasers as sources of ultraviolet light" (*id.*).

Appellant contends Anderson "teaches that the endometrium can be ablated if treated with a photosensitive composition that renders it vulnerable to ablation . . . impl[ying] that under natural conditions, the endometrium is not responsive to light ablation, which is consistent with Clarke's description that UV radiation is ineffective against endothelial lining" (App. Br. 14). Appellant contends that Anderson, "like Selman, . . . describes a method that targets a tissue layer excluded by Clarke, namely, the mucous membrane. Accordingly, the skilled artisan would also be dissuaded from combining the disclosure of Anderson and Clarke as the two references target mutually exclusive tissue layers" (*id.*).

Appellant's arguments are not persuasive. Anderson and Clarke provide evidence that one skilled in the art of tissue ablation would have

been familiar with the destructive effect of ultraviolet light on tissue in general, with or without the use of a photosensitive dye (**FF7**, **12**, **14**). Anderson teaches that endometrial tissue can be selectively ablated without damaging the myometrium, by staining the lining with a photosensitive compound, and illuminating the lining (**FF12**). We agree with the Examiner that one of skill would have expected Anderson's method to be selective for mucosal tissue, regardless of the source of the light, as long as the wavelength and intensity of the light was compatible with the photosensitive dye - which we find would have been within the level of skill in the art to determine (**FF6**).

In any case, Clarke teaches that an ultraviolet flash lamp is a conventional alternative to a laser for illuminating tissue (**FF9**). An express suggestion to substitute one for the other is not required to establish obviousness (*In re Fout*, 675 F.2d at 301).

We find that Appellant has not established that the Examiner erred in concluding that the teachings of Selman and Clarke would have led one skilled in the art to ablate a mucosal or endothelial lining overlying a muscle layer, while avoiding damage to the underlying muscle layer, by illuminating the mucosal or endothelial lining with ultraviolet light generated by a flash lamp, rather than a laser.

VII. Anderson, Clarke, and Ohtake

The Examiner rejected claims 31 and 32 as unpatentable over Anderson, Clarke, and Ohtake.

The Examiner concluded that "[i]t would have been obvious to the artisan of ordinary skill to employ a lenticular surface [in the form of a

Fresnel lens] in the method of Anderson et al in combination with Clarke, since this would provide a more even distribution of light" (Ans. 6).

Appellant contends that

> Ohtake does not teach or suggest medical use of light, [and] therefore, does not suggest why one should combine aspects of Clarke's UV therapy with Anderson's photodynamic treatment. Accordingly, Ohtake does not provide any suggestion as to why and how Anderson and Clarke's teachings can be combined or modified to . . . ablat[e] the mucosal or endothelial lining using UV light generated by a flash lamp while avoiding substantial damage to the muscle layer, as required by instant Claim 14.

(App. Br. 16.) Appellant further contends that "Ohtake is silent as to why [a] Fresnel lens should be used in an *in vivo* tissue ablation method" (*id.*).

Appellant's argument is not persuasive. As discussed above, Appellant has not established that the Examiner erred in concluding that it would have been obvious to use a UV flash lamp to ablate mucosal tissue based on the teachings of Anderson and Clarke. Moreover, Anderson teaches that even illumination of the target area is important (**FF13**), and the Examiner cited Ohtake as evidence that Fresnel lenses are conventionally used with flash lamps to provide an even distribution of light (**FF16**), and Appellant has not disputed this finding.

SUMMARY

Appellant has not established that the Examiner erred in concluding that it would have been obvious for one skilled in the art to ablate a mucosal or endothelial lining overlying a muscle layer, while avoiding damage to the underlying muscle layer, by illuminating the mucosal or endothelial lining with ultraviolet light generated by a flash lamp, rather than a laser.

Accordingly:

I. The rejection of claims 14-18, 21, 22, 25, 27, 28, 39, and 40 under 35 U.S.C. § 103(a) as unpatentable over Selman and Clarke is affirmed.

II. The rejection of claims 20, 23, and 24 under 35 U.S.C. § 103(a) as unpatentable over Selman, Clarke, and Waksman is affirmed.

III. The rejection of claims 26, 29, and 30 under 35 U.S.C. § 103(a) as unpatentable over Selman, Clarke, Waksman, and Spears is affirmed.

IV. The rejection of claims 33 and 34 under 35 U.S.C. § 103(a) as unpatentable over Selman, Clarke, and Feinbloom is affirmed.

V. The rejection of claims 35 and 36 under 35 U.S.C. § 103(a) as unpatentable over Selman, Clarke, Feinbloom, and Stanton is affirmed.

VI. The rejection of claims 14, 19, and 37-39 under 35 U.S.C. § 103(a) as unpatentable over Anderson and Clarke is affirmed.

VII. The rejection of claims 31 and 32 under 35 U.S.C. § 103(a) as unpatentable over Anderson, Clarke, and Ohtake is affirmed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

cdc

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